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THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of: John E. Sims and Dirk E. Smith — Docket No.: 0317-US

Serial No.: 09/763,498 — Group Art Unit: 1647

Filing Date: May 15, 2000 — Examiner: F. Hamud

For: Human IL-1 Epsilon DNA and Polypeptides

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

This Communication is responsive to the Office Action mailed January 24, 2002, in which the Examiner restricts the invention into groups I through IX and requires election of one of the inventions set forth by the Examiner. Applicants respectfully traverse the requirement to elect on the grounds that the claims as filed meet the unity of invention requirements. Applicants provisionally elect the invention of Group II.

The claims pending in this application are drawn to IL-1 Epsilon nucleic acids, vectors containing the nucleic acids, host cells containing the vectors, polypeptides, methods for producing the polypeptides and antibodies that bind the polypeptides. The nucleic acids of SEQ ID NO:5 are contained fully within the nucleic acids of SEQ ID NO; 7 and SEQ ID NO:12. Furthermore, the nucleic acid of SEQ ID NO:7 and the nucleic acid of SEQ ID NO:12 differ by a single nucleic acid. That is, SEQ ID NO:12 is an IL-1 Epsilon polymorphism. The polypeptides are similarly related. In order to visualize the similarity, Applicants provide herewith a PILEUP of the sequences.

The Examiner insists that SEQ ID NO:7, SEQ ID NO:5 and SEQ ID NO:12 do not share a common technical feature which is based on a common property not found in the prior art. However, the Examiner provides no evidence to support this conclusion. Furthermore, the Examiner asserts that the encoded polypeptides and the nucleic acids are different, independent and distinct chemical compounds that lack either a common structural property which distinguishes them as a group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art polypeptide or nucleic acids. Again, the Examiner provides only

conclusionary statements and provides no evidence to support the conclusion that unity of invention is not met.

With respect to the Examiner's requirement to elect one of the polypeptides (restrictions that involve Groups IV, V), the polypeptides of SEQ ID NO:7 and SEQ ID NO:13 have common structures and properties, which alone is sufficient to meet the unity of invention requirements. Applicants respectfully request that the Examiner withdraw the requirement as it relates to restricting the claimed polypeptides. In the absence of withdrawing the requirement, Applicants request that the Examiner demonstrate the basis for the lack of unity of invention.

As for the requirement to restrict the respective nucleic acid molecules, vectors, host cells and methods for preparing the polypeptides (Groups I, II, III, VI; VII), as described above, the nucleic acid molecules of SEQ ID NO:7 and 12 are structurally similar. SEQ ID NO:7 and SEQ ID NO:12 differ by one nucleotide. There is no basis for the Examiner to assert that the claim nucleic acid molecules are structurally different. Because the nucleic acids share significant structural elements, there is no basis for restricting the nucleic acids claims. Moreover, the Federal Circuit and the PTO have long recognized that claims to nucleic acids, vectors containing the nucleic acids, host cells containing the vectors and methods of using the host cells to produce a polypeptide are not separate inventions. To this end, the PTO examines these claims as one Group. Thus, the Examiner's view that claims of Groups V and VI should be restricted from each other, as well as restricted from Groups I, II and III is improper and without merit.

Finally, Applicants respectfully assert that it is improper, under unity of invention Rule 13, for the Examiner to require restriction between claims to polypeptides and claims to the nucleic acids that encode the polypeptides. The Examiner's attention is directed to Annex B Unity of Invention (PCT/AI/1 Rev.1) Example 17. This Example describes unity as present between Protein X (claim 1) and the DNA encoding protein X (Claim 1). In view of this clear mandate, Applicants request that the Examiner withdraw the requirement to restrict as between claims to polypeptide and claims to nucleic acids encoding the polypeptide.

In view of the foregoing, Applicants respectfully assert that claims to the polypeptides, claims to the nucleic acids that encode the polypeptides, claims to vectors, claims to host cells containing the vectors, and claims to processes for preparing the polypeptides meet the unity of invention requirements and are properly examined in a

single application. Accordingly, Applicants request that the Examiner withdraw the restriction requirement as it relates to the claims of Groups I, II, III, IV, V, VI, and VII. In so doing, claims 21-39 will be properly the subject of examination in this application.

In view of the provisional election and traverse, Applicant requests favorable consideration of the restriction requirement and speedy allowance of the claims.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on the date indicated below.

Date: May 14, 2002 Signed: Nanci M. Kertson
Nanci M. Kertson

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Appendix A: Multiple Alignment of the amino acid sequences of SEQ ID NOs:6, 8 and 13

```
!!AA_MULTIPLE_ALIGNMENT 1.0
PileUp of: @/tmp/GCGRMIServer/198.178.220.29-
1019766414427.pileup/pileup.list

 Symbol comparison table: GenRunData:blosum62.cmp  CompCheck: 1102

                  GapWeight: 8
            GapLengthWeight: 2

 stdout  MSF: 158  Type: P  April 25, 2002 13:26  Check: 399 ..

Name: SEQ ID NO:6  (SEQ  6)  Len:   158  Check: 2077  Weight:  1.00
Name: SEQ ID NO:8  (SEQ  8)  Len:   158  Check: 9155  Weight:  1.00
Name: SEQ ID NO:13 (SEQ 13)  Len:   158  Check: 9167  Weight:  1.00

//

     1                                                  50
SEQ  6  ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~
SEQ  8  MEKALKIDTP QQGSIQDINH RVWVLQDQTL IAVPRKDRMS PVTIALISCR
SEQ 13  MEKALKIDTP QRGSIQDINH RVWVLQDQTL IAVPRKDRMS PVTIALISCR

        51                                                 100
SEQ  6  ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~EK DIMDLYNQPE
SEQ  8  HVETLEKDRG NPIYLGLNGL NLCLMCAKVG DQPTLQLK
SEQ 13  HVETLEKDRG NPIYLGLNGL NLCLMCAKVG DQPTLQLK
                                                 ** **********

        101                                                150
SEQ  6  PVKSFLFYHS QSGRNSTFES VAFPGWFIAV SSEGGC~~~~ ~~~~~~~~~~
SEQ  8                                        PLIL TQELGKANTT
SEQ 13                                        PLIL TQELGKANTT
        ********** ********** ********** ******

        151
SEQ  6  ~~~~~~~~
SEQ  8  DFGLTMLF
SEQ 13  DFGLTMLF

* indicates identity between the three polypeptides compared
```

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Appendix B: Multiple Alignment of the amino acid sequences of SEQ ID NOs:5, 7 and 12

```
!!NA_MULTIPLE_ALIGNMENT 1.0
PileUp of: @/tmp/GCGRMIServer/198.178.220.29-
1019765667622.pileup/pileup.list


Symbol comparison table: GenRunData:pileupdna.cmp  CompCheck: 6876

                 GapWeight: 5
            GapLengthWeight: 1

 stdout  MSF: 477  Type: N  April 25, 2002 13:14  Check: 8750 ..

 Name: SEQ 5  (SEQ ID NO:5)   Len:   477  Check: 2386  Weight:  1.00
 Name: SEQ 7  (SEQ ID NO:7)   Len:   477  Check: 3077  Weight:  1.00
 Name: SEQ 12 (SEQ ID NO:12)  Len:   477  Check: 3287  Weight:  1.00

//

        1                                                      50
SEQ 5   ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~
SEQ 7   ATGGAAAAAG CATTGAAAAT TGACACACCT CAGCAGGGGA GCATTCAGGA
SEQ 12  ATGGAAAAAG CATTGAAAAT TGACACACCT CAGCGGGGGA GCATTCAGGA


        51                                                    100
SEQ 5   ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~
SEQ 7   TATCAATCAT CGGGTGTGGG TTCTTCAGGA CCAGACGCTC ATAGCAGTCC
SEQ 12  TATCAATCAT CGGGTGTGGG TTCTTCAGGA CCAGACGCTC ATAGCAGTCC


        101                                                   150
SEQ 5   ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~
SEQ 7   CGAGGAAGGA CCGTATGTCT CCAGTCACTA TTGCCTTAAT CTCATGCCGA
SEQ 12  CGAGGAAGGA CCGTATGTCT CCAGTCACTA TTGCCTTAAT CTCATGCCGA


        151                                                   200
SEQ     ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~
SEQ  7  CATGTGGAGA CCCTTGAGAA AGACAGAGGG AACCCCATCT ACCTGGGCCT
SEQ 12  CATGTGGAGA CCCTTGAGAA AGACAGAGGG AACCCCATCT ACCTGGGCCT
```

```
          201                                                       250
SEQ  5    ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~ ~~~~~~~~~~
SEQ  7    GAATGGACTC AATCTCTGCC TGATGTGTGC TAAAGTCGGG GACCAGCCCA
SEQ 12    GAATGGACTC AATCTCTGCC TGATGTGTGC TAAAGTCGGG GACCAGCCCA


          251                                                       300
SEQ  5    ~~~~~~~~~~ ~~~~GAAAAG GATATAATGG ATTTGTACAA CCAACCCGAG
SEQ  7    CACTGCAGCT GAAG
SEQ 12    CACTGCAGCT GAAG
                     ****** ********** ********** **********

          301                                                       350
SEQ  5    CCTGTGAAGT CCTTTCTCTT CTACCACAGC CAGAGTGGCA GGAACTCCAC
SEQ  7
SEQ 12
          ********** ********** ********** ********** **********

          351                                                       400
SEQ  5    CTTCGAGTCT GTGGCTTTCC CTGGCTGGTT CATCGCTGTC AGCTCTGAAG
SEQ  7
SEQ 12
          ********** ********** ********** ********** **********

          401                                                       450
SEQ  5    GAGGCTGTCC TCTCATCCTT ACCCAAGAAC TGGGGAAAGC CAACACTACT
SEQ  7
SEQ 12
          ********** ********** ********** ********** **********

          451                       477
SEQ  5    GACTTTGGGT TAACTATGCT GTTTTAA
SEQ  7
SEQ 12
          ********** ********** *******
```

* indicates identity between the three polynucleotides compared